APR 5 - 2007

K063458

# Premarket Notification (510(k)) Summary

## 1. Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

| | |
|---|---|
| Contact Person: | Maria Ruiz<br>Senior Regulatory Affairs Associate |
| Phone Number: | (651) 736-2733 |
| FAX Number: | (651) 737-5320 |


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|---|---|
| Date of Summary: | November 13, 2006 |

## 2. Device Name and Classification:

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|---|---|
| Common or Usual Name: | IV Dressing with CHG |
| Proprietary Name: | 3M™ Tegaderm™ CHG Dressing<br>(Chlorhexidine Gluconate Securement Dressing) |
| Classification Name: | Dressing, Unclassified |
| Performance Standards: | None |

## 3. Predicate Devices:

- 3M™ Tegaderm™ Transparent Dressings (16xx series) (K973036)
- Integra LifeSciences BIOPATCH Antimicrobial Dressing (K003229)

## 4. Description of Device:

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes to meet the needs of the caregiver.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The dressing is a barrier to liquid (waterproof), bacteria and yeast, and protects the IV site from outside contamination. The pad absorbs up to eight times its weight in fluid. *In vitro* testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast in the dressing.

Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 - 2007

3M Health Care
% Ms. Maria Ruiz
Senior Regulatory Affairs
Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K063458
Trade/Device Name: 3M™ Tegaderm™ CHG Dressing,
(Chlorhexidine Gluconate Securement Dressing)
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 30, 2007
Received: April 2, 2007

Dear Ms. Ruiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

**510(k) Number (if known):** K063458

**Device Name**: 3M™ Tegaderm™ CHG Dressing,
(Chlorhexidine Gluconate Securement Dressing)

**Indications for Use:**

3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

Prescription Use X OR Over-The-Counter-Use ____

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative,**
**and Neurological Devices**

**510(k) Number** K063458